



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

National Institute of Mental Health Recruitment and Milestone Reporting System

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on August 2, 2013, page 46994 and allowed 60-days for public comment. One public comment was received regarding human subjects research recruitment and retention and the perception of coercion. The recruitment and enrollment procedures proposed by a NIMH-funded clinical trial are reviewed and approved by an IRB of record, which has agreed to review human subject research projects in accordance with 45 CFR Part 46 and its Federal-wide Assurance. The IRB of record ensures that the possibility of coercion or undue influence is minimized, that an investigator seeks consent only under circumstances that provide the prospective subject/representative sufficient opportunity to consider whether or not to participate. To address these concerns, we plan to add a statement about human subject protections to the policy and add a link to the human subjects training on the policy webpage. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of

Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or E-mail your request, including your address to: nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION

National Institute of Mental Health Recruitment Milestone Reporting System- Existing collection in use without OMB control number - National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: The Recruitment Milestone Reporting (RMR) System allows NIMH staff to monitor more accurately the recruitment of participants in NIMH-sponsored clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure proper use of the grant funds. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, and potentially increase efficiency in our funding process.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,531.

Estimated Annualized Burden Hours

Form	Type of Respondent	Number of Respondents	Frequency of Response	Average Burden per Response (in hours)	Total Annual Burden Hours
NIMH Recruitment Milestone Reporting	Principal Investigators/ Research Assistant	675	3	75/60	2,531

Dated: February 18, 2014

Keisha Shropshire

Project Clearance Officer

NIMH, NIH

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